K080694

510(k) Summary

MAY 15 2008

Device Proprietary Name:	OsteoMed Modular Locking Fixation System
Device Common Name:	Modular Locking Fixation System
Classification Name:	JEY, Bone Plate
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-4601
Contact Person:	Piedad Peña
Date Prepared:	March 10, 2008

Summary:

This submission describes the OsteoMed Modular Locking Fixation System indicated for fracture fixation in cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction. The implants and drills are intended for single use only.

The ***OsteoMed*** *Modular Locking Fixation System* is comprised of plates, screws and instrumentation utilized in the fixation of craniofacial, maxillofacial and mandibular fractures. The locking screw and plate interface allows up to 20 degrees of angulation within screw placement. The plating system allows for the use of locking standard screws, locking Auto-Drive™ screws, standard non-locking screws, safety screws and Auto-Drive™ screws, as needed. The screws are made from Titanium Alloy (ASTM F-136). The plates are made from Titanium Alloy (ASTM F-136) or commercially pure Titanium (ASTM F-67). Drill bits, plate bending pliers, plate holding forceps, plate cutters, drill guides, cannulae, taps, countersinks, and screwdrivers to facilitate the placement of screws and modification of plates will also be a part of the system.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Synthes K063790, Stryker K022185, KLS K032442, OsteoMed (K911936/Addendum K924138 and K030448), and Lorenz (K063052).

OsteoMed also notes, that some sections of this system could have been letter to file based on the OsteoMed previously cleared submissions. The intent of this submission is to present the system as complete modules and include the

changes to the designs, which would allow up to 20 degrees of angulation within the locking screw and plate interface.

The locking screw and plate interface designs and operational principles addressed in this submission are based on similarities to the predicate devices Synthes (K063790), Stryker (K022185), and KLS (K032442) based on their promotional materials and labeling.

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Modular Locking Fixation System does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Ms. Piedad Peña
Regulatory Affairs Specialist
OsteoMed L.P.
3885 Arapaho Road
Addison, Texas 75001

Re: K080694
Trade/Device Name: OsteoMed Modular Locking Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 10, 2008
Received: March 11, 2008

Dear Ms. Peña:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080694

Indications for Use

510(k) Number (if known): _____

Device Name: OsteoMed Modular Locking Fixation System

Indications for Use:

The OsteoMed Modular Locking Fixation System is intended for fracture fixation in cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

The OsteoMed Modular Locking Fixation System implants and drills are intended for single use only.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

(Posted November 13, 2003) 510(k) Number: K080694